

Amendments to the Claims

This listing of the claims replaces all previous claims.

Listing of the Claims

1-18 (Canceled)

19. (CURRENTLY AMENDED) A method of preparing a gel delivery system comprising gel particles for topical application of at least one active agent, said method comprising:

(a) forming an aqueous solution of a polymeric gelling agent, said aqueous solution being maintained at a first temperature above the gelling point of said polymeric gelling agent, the solution being gellable at a lower temperature below the solution temperature, said aqueous solution forming a gelling agent solution further comprising, ~~the gelling agent solution having~~ dispersed therein, said at least one active and a restraining polymer;

(b) discharging the gelling agent solution through a discharge orifice into a moving stream of hydrophobic liquid and forming droplets of said gelling agent solution, said hydrophobic liquid being at a second temperature below the gelling point of said gelling agent solution, the hydrophobic liquid being immiscible with the gelling agent solution ;

wherein the gel particles coalesce from the gelling agent solution in the hydrophobic liquid stream through the gelling of said droplets with said active and said restraining polymer entrapped therein, and wherein the restraining polymer has sufficient molecular weight to prevent egress of the restraining polymer from the gel particles, and wherein said restraining polymer is bonded to the at least one active agent in the gelling agent solution so as to retain the at least one active agent in the gel particles.

20. (CURRENTLY AMENDED) A method according to claim 19 wherein the hydrophobic liquid stream is contained in a conduit, the discharge orifice is located in the conduit and wherein the hydrophobic liquid stream moves past the discharge orifice and exerts a force on said

solution in the discharge orifice, the force acting to withdraw ~~the~~ said solution from the discharge orifice.

21. (PREVIOUSLY PRESENTED) A method according to claim 19 comprising discharging the gelling agent through an injection tube, the injection tube terminating in the discharge orifice wherein the discharge orifice is positioned in the moving stream of hydrophobic liquid.

22. (PREVIOUSLY PRESENTED) A method according to claim 21 comprising containing the hydrophobic liquid stream in a conduit wherein the liquid stream flows through the conduit and wherein the injection tube extends into the conduit.

23. (PREVIOUSLY PRESENTED) A method according to claim 22 wherein the conduit has a rectilinear portion and the injection tube extends approximately perpendicularly into the rectilinear portion of the conduit.

24. (CURRENTLY AMENDED) A method according to claim 22 wherein the conduit has a cross-sectional area of from about 4 to about 100 times the cross-sectional area of the injection tube; ~~optionally at least 25 times.~~

25. (PREVIOUSLY PRESENTED) A method according to claim 22 wherein the ratio of the flow rate of the gelling agent solution to the flow rate of the hydrophobic liquid is between about 1:2 and 1:50.

26. (PREVIOUSLY PRESENTED) A method according to claim 22 wherein the injection tube has an internal diameter of from about 0.05 to about 10 mm.

27. (PREVIOUSLY PRESENTED) A method according to claim 22 wherein the conduit has a cross-sectional area of from about 4 to about 400 times the cross-sectional area of the injection tube, the ratio of the flow rate of the gelling agent solution to the flow rate of the hydrophobic liquid is between about 1:2 and 1:50 and the injection tube has an internal diameter of from about 0.05 to about 10mm.

28. (PREVIOUSLY PRESENTED) A method according to claim 22 comprising cooling the hydrophobic liquid upstream of the discharge orifice.

29. (PREVIOUSLY PRESENTED) A method according to claim 28 comprising separating the gel particles from the hydrophobic liquid and recirculating the hydrophobic liquid to the discharge orifice.

30. (CURRENTLY AMENDED) A method according to claim 19 wherein the hydrophobic liquid stream is contained in a conduit, the gelling agent is discharged through an injection tube and the injection tube terminates in the discharge orifice, the discharge orifice being located in the conduit and wherein the hydrophobic liquid stream moves past the discharge orifice and exerts a force on the solution in the discharge orifice, the force acting to withdraw the solution from the discharge orifice.

31. (PREVIOUSLY PRESENTED) A method according to claim 30 wherein the gel particles are capable of being manually crushed and applied topically by an end user.

32. (CURRENTLY AMENDED) A method according to claim 30 wherein the gelling agent comprises a pH stable water-soluble polymer ~~optionally~~ selected from the group consisting of ~~synthetic polymers~~, vinyl polymer and copolymers, acrylamide polymers and copolymers, ~~natural polymers~~, polysaccharides, proteins, synthetically modified polysaccharide, synthetically modified proteins, botanically derived gels and carbopol.

33-36 (Canceled)

37. (PREVIOUSLY PRESENTED) A method according to claim 19 comprising pumping the gelling agent solution from a heated vessel containing a bulk supply of the gelling agent solution to the discharge orifice.

38. (PREVIOUSLY PRESENTED) A method according to claim 37 comprising recirculating the hydrophobic liquid through a cooled tank.

39. (PREVIOUSLY PRESENTED) A method according to claim 38 comprising recirculating a coolant between a chiller and the cooled tank to maintain a desired low temperature in the tank.

40. (PREVIOUSLY PRESENTED) A method according to claim 37 comprising flowing the hydrophobic liquid containing gel particles over a screen to separate the gel particles from the hydrophobic liquid.

41. (PREVIOUSLY PRESENTED) A method according to claim 19 comprising pumping the gelling solution from a heated vessel containing a bulk supply of the gelling agent solution to the discharge orifice, recirculating the hydrophobic liquid through a cooled tank, recirculating a coolant between a chiller and the cooled tank to maintain a desired low temperature in the tank and flowing the hydrophobic liquid containing gel particles over a screen to separate the gel particles from the hydrophobic liquid.

42. (CURRENTLY AMENDED) A method according to claim 19 wherein the discharge orifice includes an inner diameter and the moving stream of hydrophobic liquid has a velocity; the method further comprising selecting the ~~discharge size~~ inner diameter of the discharge orifice and the velocity of the moving stream of hydrophobic liquid according to the desired gel particle size.

43. (PREVIOUSLY PRESENTED) A method according to claim 19 wherein the flow rate of the hydrophobic liquid is greater than the flow rate of the gelling agent solution.

44. (PREVIOUSLY PRESENTED) A method according to claim 19 comprising discharging the gelling agent solution into the cold hydrophobic liquid stream at a flow rate of from about 2.5 to 6.2 ml/min wherein the hydrophobic liquid stream moves with a flow rate of about 10 ml/min to about 300 ml/min.

45. (PREVIOUSLY PRESENTED) A method according to claim 19 operated to make beads of from about 2.8 to about 4 mm diameter or from about 0.4 to about 0.7 mm diameter.

46-63 (Canceled)

64. (PREVIOUSLY PRESENTED) Gel beads produced by a method according to claim 19.

65. (Canceled)

66. (PREVIOUSLY PRESENTED) The method of claim 19, wherein the restraining polymer is ionically bonded to the at least one active agent.

67. (PREVIOUSLY PRESENTED) The method of claim 66, wherein said first temperature ranges from between about 70°C and about 100°C.

68. (CURRENTLY AMENDED) The method of claim 66, wherein said second temperature is ~~below~~ about 30°C or below.

69. (CURRENTLY AMENDED) A method of preparing a gel delivery system comprising gel particles for topical application of at least one active agent, said method comprising:

a) forming an aqueous solution of a polymeric gelling agent, the solution being gellable at a temperature below the solution temperature, said aqueous solution having a temperature ranging from between about 70°C and about 100°C; said solution forming a gelling agent solution further comprising, ~~said gelling agent solution having~~ dispersed therein, said at least one active agent and a restraining polymer;

b) discharging the gelling agent solution through a discharge orifice into a moving stream of hydrophobic liquid and forming droplets of said gelling agent solution, the hydrophobic liquid being immiscible with the gelling agent solution and being at a temperature ~~of~~ below about 30°C or below, said temperature below the gelling agent solution gelling point;

wherein the gel particles coalesce from the gelling agent solution in the hydrophobic liquid stream through the gelling of said droplets with said active and said restraining polymer entrapped therein, and wherein the restraining polymer has sufficient molecular weight to prevent egress of the restraining polymer from the gel particles, said restraining polymer being ionically bonded to the at least one active agent in the gelling agent solution so as to retain the at least one active agent in the gel particles.

70. (PREVIOUSLY PRESENTED) A gel delivery system, comprising gel particles for topical application of at least one active agent produced according to the method of claim 19.